Department of Veterans Affairs **VHA DIRECTIVE 2004-028**
Veterans Health Administration
Washington, DC 20420 **June 25, 2004**

ENSURING CORRECT SURGERY AND INVASIVE PROCEDURES

PURPOSE: This Veterans Health Administration (VHA) Directive provides specific information on what steps must be taken to ensure that the indicated surgical or invasive procedure is performed on the correct patient, at the correct site, and if applicable with the correct implant. ***NOTE:*** *Correct site includes the correct side (i.e., left or right) and the precise anatomical part, such as a specific finger.*

2. BACKGROUND

a. Wrong site, wrong patient, and wrong implant procedures are relatively uncommon adverse events in health care but are often devastating when they occur. Specifically, this Directive provides guidance on invasive procedures performed in settings such as patient rooms and intensive care units.

b. There are five steps used in the VHA to ensure correct surgery:

(1) The consent form is administered and executed properly,

(2) The operative site is marked,

(3) The patient is actively identified using required techniques,

(4) A "time-out" briefing is conducted in the operating room (OR) prior to starting the procedure, and

(5) Two members of the OR team review pertinent radiological images prior to commencing the surgical procedure.

c. Attachments A, B, and C address the processes required to precede surgical and invasive procedures performed in ORs, dedicated surgical suites (inpatient or ambulatory), and other dedicated procedure rooms such as endoscopy suites. ***NOTE:*** *Any reference to an "operating room" or "OR" throughout this document should be understood to include and pertain to similar dedicated inpatient or ambulatory procedure rooms without regard to the name used locally to describe the room or suite. The requirements for an OR in an ambulatory setting are described in VHA Handbook 1102.5: Criteria and Standards for Performance of Ambulatory (Same-Day) Surgery Performed in Ambulatory or Dedicated Surgical Suites (available at http://vaww.va.gov/publ/direc/health/handbook/1102.5hb5-20-03.pdf).*

d. Attachment D addresses the processes that are required to precede invasive procedures that are performed in clinical settings other than ORs, such as the inpatient bedside, intensive

care units, emergency rooms, physician's offices, etc. ***NOTE:*** *These settings are addressed separately because the assumptions underlying the steps required in Attachments A, B and C do not always apply to non-OR settings, for example, the assumptions that multiple practitioners and staff will be involved and that the patient will be moved from a location where the patient is prepared for surgery to a different location where the surgery will be performed.*

e. Attachment E describes the surgical and other invasive procedures that are covered by this Directive.

f. To facilitate the development of local procedures and policy documents, Attachment F contains a sample facility policy.

g. Attachment G provides additional strategies, techniques, and tools that are not required by this Directive, but which merit consideration in the development and implementation of facility policies and procedures.

h. Attachment H contains a flowchart for use in determining if a procedure must follow the processes in Attachments A, B, and C, or if the abbreviated processes in Attachment D apply.

3. POLICY: It is VHA policy that in VHA facilities where surgery and invasive procedures are performed specific steps must be implemented in order to reduce the likelihood of incorrect surgeries (see Att. A, Att. B, and Att. C) and other incorrect invasive procedures (see Att. D and Att. E).

4. ACTION: The Facility Director is responsible, for ensuring that, no later than July 1, 2004:

a. Except in cases of medical or surgical emergencies, or those rare situations where certain steps are impossible to complete, the five steps listed in preceding paragraph 2, and detailed in Attachments A, B, and C, must be performed for those procedures performed in an OR setting. Furthermore, if a step required by this Directive has not been performed, the next step must be delayed until the previous step has been completed. For surgical procedures, steps in Attachment C cannot start until the steps in Attachment B are completed; and those steps in Attachment B cannot start until the steps in Attachment A are completed. For invasive procedures, the steps in Attachment D must be followed as described. ***NOTE:*** *In the rare cases where the required steps are not all followed, the justification for the deviation(s) must be documented.*

b. A facility policy document is put into effect that describes the required specific steps (see Att. A, Att. B, Att. C, Att. E, and Att. F.) that must be implemented in order to reduce the likelihood of incorrect surgical and invasive procedures.

c. The execution of these steps is documented in the patient's record (see Att. A, Att. B, Att. C, Att. D, and Att. E).

d. The implementation of the steps and conformance to the facility's policy document(s) is monitored for compliance.

5. REFERENCES

a. VHA Handbook 1004.1. VHA Informed Consent for Clinical Treatments and Procedures. Available at: http://vaww.va.gov/publ/direc/health/handbooks/1004-1hk .

b. VHA Handbook 1102.5. Criteria and Standards for Performance of Ambulatory (Same Day) Surgery Performed in Ambulatory or Dedicated Surgical Suites. Available at http://vaww.va.gov/publ/direc/health/handbook/1102.5hb5-20-03.pdf

c. JCAHO Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. Available at: http://www.jcaho.com/accredited+organizations/patient+safety/universal+protocol/wss_universal+protocol.htm

d. JCAHO 2004 National Patient Safety Goals. Available at: http://www.jcaho.com/accredited+organizations/patient+safety/04+npsg/index.htm .

e. American Academy of Orthopedic Surgeons Advisory Statement on Wrong Site Surgery: Statement 1015, October 2003, http://www.aaos.org/wordhtml/papers/advistmt/1015.htm .

6. FOLLOW-UP RESPONSIBILITIES: The VHA National Center for Patient Safety (10X) and the Office of Patient Care Services (111B) share responsibility for the development and contents of this Directive. Questions regarding this directive may be addressed to the National Center for Patient Safety at (734) 930-5890.

7. RESCISSION: VHA Directive 2002-070 is rescinded. This VHA Directive expires June 30, 2009.

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Attachments

DISTRIBUTION: CO: E-mailed 6/28/04
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 628/04

ATTACHMENT A

MINIMUM PRE-OPERATIVE PROCEDURES
(Days to approximately 1 hour before surgery)

1. The consent form to be signed by the patient (or the individual legally authorized to consent on behalf of the patient) pre-operatively must state the procedure site, including laterality if applicable; the name and a brief description of the procedure; and the reason (condition or diagnosis) for which the procedure is to be performed. More information is available in VHA Handbook 1004.1, VHA Informed Consent for Clinical Treatments and Procedures.

ACTION: The medical center Director, or designee, is responsible for ensuring that facility consent forms facilitate providing the required information on the:

a. Site of the procedure (location on the body);

b. Laterality of the procedure (side of the body), if applicable;

c. Name and brief description of the procedure; and

d. Reason (condition or diagnosis) for the procedure.

Rationale: *To improve patient safety, documenting the preceding information helps ensure that data critical to the proper identification and verification of the patient and procedure is readily available. To facilitate clear communication with the patient, this documentation needs to be in language that the patient understands.*

NOTE: *In order to give informed consent, the patient must have decision-making capacity, be fully informed, and participate voluntarily (see VHA Handbook 1004.1 - Informed Consent for Clinical Procedures and Treatments). A patient should be presumed to have decision-making capacity unless an appropriate clinical evaluation determines that the patient lacks decision-making capacity, or the patient is a minor, or the patient has been ruled incompetent by a court of law. It should be noted that patients who receive sedation or pain medication may still be capable of giving informed consent. However, for routine procedures that require the use of sedation or analgesia, signature consent should normally be obtained before the patient is pre-medicated. For additional information about decision-making capacity, see the VHA National Ethics Committee report on this topic:*
http://vaww1.va.gov/vhaethics/download/TenMythsReport.doc.

2. The medical center Director, or designee, is responsible for putting procedures and methods in place that specify pre-operative marking of the operative site by a physician member of the operating team (surgeon, resident, fellow), or other privileged provider, performing the invasive procedure. The physician, or other privileged provider, who marks the site must be a member of the operating team assigned to be present in the operating room during the procedure. The purpose for marking the site is to clearly indicate the procedure site and needs to be done with the involvement of the patient whenever possible. Indicating the site with appropriate precision needs to be the primary consideration when placing the mark. For emergencies these

procedures need to be applied to the extent possible, and facilities must have policies and procedures in place that specify when marking is not required. These policies must include provisions for patients that consent for surgery but refuse to have the surgical site marked, which allow the operation to proceed.

ACTION: The medical center Director, or designee, is responsible for specifying exactly how physicians or other privileged providers are to mark operative sites and document that the marking process has been completed: a typical standard practice is to use an appropriate marking pen and to mark the site with the physician's initials or an "X." The method and type of mark to be made (initials, X, etc.) must be consistent for the entire institution. The need for a different sized mark or slightly different mark for some sites, such as a site on the face for ophthalmic procedures is understood. The site needs to be marked so that it is unambiguous; for example, for surgery on a finger, the finger is to be marked rather than the palm or back of the hand. Whenever possible the mark needs to be placed so that it will be visible in the operative field after of the site is prepped and draped. Always use ink that will withstand pre-surgical preparation of the operative site. Do not use adhesive stickers to mark a site.

Rationale: *Marking the site makes clear where the surgery is to be performed. Having the surgeon or other designated member of the surgical team mark the site will help ensure that the mark is placed at the correct site. Although patients need to corroborate the site as the surgeon marks it when it is possible to do so, patients are not to mark the site.*

3. To prevent confusion non-operative sites must not be marked, unless required for another aspect of care.

ACTION: The medical center Director, or designee, is responsible for ensuring that local policy explicitly states that the non-operative sites must not be marked, unless required for another aspect of care.

Rationale: *When non-operative sites are marked, these marks may cause confusion and have the opposite of the intended effect. For example, "X" may signify "operate here" to one person and "don't operate here" to another.*

4. Surgical procedures for which the requirement to mark the operative site is waived in the OR setting are:

a. Endoscopic or other procedures performed through the mouth or anus. This does not include procedures performed on or near the anus such as removal of an external hemorrhoid or repair of an anal fistula, or procedures performed on adjacent anatomical locations such as the perineum, buttocks, or lower back, which do require a mark.

b. Oral surgery and other procedures where marking the site would require marking a mucous membrane rather than skin.

5. There is a requirement to mark virtually all operative sites, including those on the midline, face, and groin (except as noted in paragraph 4). However, in cases where there is a patient or practitioner concern regarding marking a particular site, for example based on the site being awkward or problematic to mark (such as the perineum), a special-purpose wristband can

substitute for a marked site. In practice, this means that all patients (except as in paragraph 4) must have either their operative site marked or be wearing a special-purpose wristband prior to the steps described in Attachments B and C, and that if a wristband is used that the wristband must be checked in the subsequent steps rather than the marked site. When a special-purpose wristband is substituted for a marked site, the anatomical site of the procedure and the name of the procedure must be written on the wristband. A special-purpose wristband with the name of the procedure and the site (without indicating the side) can also be substituted for a mark for cases when the side may be selected based on a real-time clinical decision in the OR, such as the insertion of a cardiac catheter in the left or right groin. This method should not be used for sites for which the side is known and are easy to mark, but for which the precise site of the incision(s) may be determined or adjusted in the OR, such as a laparoscopic cholecystectomy. If a wristband is used in lieu of marking a site, it must be affixed by the practitioner who will perform the procedure, or be initialed by the practitioner after being affixed by another member of the team. If a wristband is used instead of marking the site, the wristband must be accessible to be checked when the "timeout" step occurs; this may preclude final site preparation before the timeout in some cases.

6. For spinal surgery, marking the site to be operated on with a pen is frequently inadequate to indicate the vertebral body or intervetebral space that will be operated on. In these cases, procedures identified by the American Academy of Orthopedic Surgeons (AAOS) should be followed: "In spine surgery or when the bone or level is not identifiable visually, surgeon takes an intraoperative X-ray using markers that do not move to confirm the site." (AAOS Advisory Statement 1015, October 2003, available at http://www.aaos.org/wordhtml/papers/advistmt/1015.htm)

ATTACHMENT B

MINIMUM PROCEDURES BEFORE THE PATIENT ENTERS THE OPERATING ROOM

(Usually an hour or less before surgery)

1. The staff must ask the patient to verbally state (not confirm): (a) their name, (b) their full social security number (SSN) or birth date, and (c) the location on their body at which they understand the procedure will take place.

2. These responses must be checked by staff against the completed consent form, marked site, and patient identification band, as applicable. This must occur in the immediate pre-operating room (OR) environment before taking the patient into the OR, for example in the hallway adjacent to the OR, etc., but not in the patient's room. Whenever possible, in cases where patients cannot provide the correct responses themselves, another person with knowledge of the patient, such as a family member, should be asked to state the name of the patient and the site to be operated on.

3. Once this active identification is performed, the staff member who has performed the identification must stay with the patient until the patient is transported into the OR. For emergencies these procedures need to be applied to the extent possible.

ACTION: The medical center Director, or designee, is responsible for establishing which personnel or job position(s) are to be assigned the task of asking the patient to state the patient's identity and what the patient understands to be the site of the upcoming procedure. In addition, it must be established how the patient's answers are to be documented and checked against local documents, including the consent form.

Rationale: *Asking the patient to state rather than confirm their name helps prevent miscommunication and wrong-patient procedures. Patients who are hard-of-hearing or distracted by illness or other temporary or permanent disability may say "yes" to a name that is not theirs, but it is very unlikely that they will misstate their name and birth date or social security number when asked. Asking the patient to state where the patient expects to be operated on is a final check prior to the provision of anesthesia, after which the patient will likely be unable to intervene on his or her own behalf. Verifying the information physically and temporally close to the place and time of the procedure helps prevent wrong patient procedures. Verifying the information in the patient's room would be less effective in reducing the vulnerability to an adverse outcome.*

ATTACHMENT C

MINIMUM OPERATING ROOM PROCEDURES
(Minutes to seconds before surgery or invasive procedure begins)

1. The medical center Director, or designee, is responsible for ensuring that procedures are in place that require verification of the correct patient, the correct procedure, the correct site, and the correct implant (where applicable) by operating room personnel in the Operating Room (OR) prior to the start of the operation, and at a time when the patient and required OR personnel are present in the OR. In most or many cases the patient will be under sedation or unconscious when this verification occurs and is not expected to participate in this process.

ACTION: The medical center Director, or designee, is responsible for establishing a specific procedure by which members of the OR team verify their agreement as to the intended surgery prior to the start of the procedure. A standard method is a "time out," during which a designated member of the OR team states the name of the patient, the procedure to be performed, the location of the site (including laterality if applicable), the required position of the patient (e.g., supine), and the specifications of the implant to be used (if applicable). After the statement, other members of the team verbally state that they concur with this information before the procedure begins. At minimum, this process must include the surgeon, the circulating nurse, and the anesthesia provider. For procedures involving special equipment or technology, the surgical technologist must also participate in the time out. Successful completion of this process must be documented. If a wristband is used instead of marking the site, the wristband must be accessible to be checked when the "timeout" step occurs; this may preclude final site preparation before the "time out" in some cases.

Rationale: *This makes sure everyone "is on the same page."*

2. The medical center Director, or designee, is responsible for ensuring that, when imaging data are used to determine or confirm the operative site, procedures are in place that require two members of the operating team to verify, prior to the start of a procedure, that the relevant images for the correct patient are available, properly labeled, and properly presented.

ACTION: For procedures during which physicians will refer to pre-existing images, the medical center Director, or designee, is responsible for ensuring that a method for documenting that two members of the OR team have confirmed that the images are available, correct, properly labeled, and properly presented. The surgeon performing the operation bears the primary responsibility for making clinical and technical decisions such as determining that available images are correct for the situation. The role of the second check by another member of the operating team is to confirm basic information, such as the correct patient name and identification number. Because the second check requires minimal technical expertise, it does not necessarily need to be performed by another surgeon or physician qualified to perform the operation.

Rationale: *Errors in determining appropriate site due to lack of availability or improper labeling of images is a real vulnerability and methods to mitigate this vulnerability must be in place.*

ATTACHMENT D

ENSURING CORRECT INVASIVE PROCEDURES IN CLINICAL SETTINGS OUTSIDE OF THE OPERATING ROOM

1. When an invasive or surgical procedure is planned for a clinical setting other than an operating room (OR), a condensed version of the processes for OR settings (as described in Att. A, Att. B, and Att. C) may be employed. Attachments A, B, and C provide specific information on the five steps that must be taken in an OR setting to ensure that the correct surgical procedure is performed on the correct patient, on the correct site and with the correct implant, if applicable.

a. Execution of the five steps can be summarized as follows:

(1) the consent form is executed properly,

(2) the operative site is marked,

(3) the patient is actively identified using required techniques,

(4) a "time-out" briefing is conducted in the OR prior to starting the procedure, and

(5) two members of the OR team review pertinent imaging data prior to commencing the surgical procedure. ***NOTE:*** *See Appendix H for a flowchart that presents a summary version of the requirements to ensure correct invasive procedures in all clinical settings.*

b. A specific example of condensed version of the "five-step" process for a procedure that would typically be performed in the patient's room follows: "Thoracentesis performed at bedside in a hospital." -- The physician determines that the patient requires left-sided thoracentesis. The physician discusses the procedure with the patient and secures signature consent. At the time of the consent, the physician marks the site. An hour later when the procedure is to be performed, another member of the clinical staff, who will assist the physician, confirms the patient's identity by asking the patient's name and birth date and checking it against the identification (ID) band and consent form. The physician reviews with the patient and other member of the clinical staff: the patient's name, the name of the procedure and the correct site and side on which it is to be performed. If the review of imaging data is necessary, the physician and other member of the clinical staff review the appropriate images together to ensure that they are for the correct patient and correct side. The physician performs the thoracentesis with assistance from the other member of the clinical staff.

2. <u>For surgical and other invasive procedures that require that a practitioner obtain a patient's signature on a Department of Veterans Affairs (VA) authorized consent form, as defined in Attachment E, the basic requirements of the "five steps" of the VHA Ensuring Correct Surgery Directive apply.</u> As described in the preceding paragraph, these may be incorporated into a condensed version as appropriate.

3. Invasive procedures for which the requirement to mark the operative site is waived are:

a. Endoscopic and other procedures performed through the mouth or anus performed in a non-OR setting. This does not include procedures performed on or near the anus, or procedures performed on adjacent anatomical locations such as the perineum, buttocks, or lower back.

b. Oral surgery, tooth extractions, and other procedures where marking the site would require marking a mucous membrane rather than skin. For dental extractions, a radiograph or diagram of the mouth showing the tooth (teeth) planned for extraction should be marked and reviewed with the patient.

c. Procedures performed in non-OR settings where the practitioner is in the physical presence of the patient from the time of signature consent, through to the time when the procedure is performed.

d. Two specific examples of these situations follow:

(1) Extraction of multiple teeth (ambulatory clinic or office setting) – One dentist sees the patient for an office visit and recommends extraction of two teeth. At this appointment, the same dentist discusses the procedures with the patient and obtains signature consent. The signature consent should include the VA authorized consent form , and VA Form 10-2570, Oral Examination Findings and Treatment Recommendations, or local equivalent, which requires the dentist to specify the exact teeth to be extracted using the required standard for numbering teeth. The office clerk provides the patient with a follow-up appointment 10 days later with a different dentist. At the second appointment, the dental assistant identifies the patient by asking the patient to state their name and full SSN and confirms with the patient that two extractions are to be performed and the location of the teeth. When the dentist greets the patient in the dental chair, the dentist reviews with the patient the planned procedures and a dental diagram or dental radiograph that has the teeth planned for extraction marked. The pertinent radiological images are also reviewed with the dental assistant prior to the procedures (at this time or earlier); both the dentist and assistant verbally confirm the planned extractions, including tooth numbers, to assure consistency with the consent form. If a dental implant is to be used, the planned site and availability of the correct implant is also confirmed.

(2) Surgical removal of a superficial mole in an office or ambulatory clinic setting. The physician greets the patient and confirms patient identity by asking the patient to state their name and birth date or social security number. They discuss the procedure in detail, and signature consent is obtained. The procedure is performed and excised tissue submitted to the Pathology Laboratory for evaluation. It was not necessary to mark the site because the physician was in the presence of the patient from the time of securing signature consent through the start of the procedure. There were no relevant images to review so that step did not apply in this case.

4. There is a requirement to mark virtually all sites of invasive procedures described in Attachment E, including those on the midline, face, and groin (except as noted in paragraph 3 of this attachment). However, in cases where there is a patient or practitioner concern regarding marking a particular site, for example based on the site being awkward or problematic to mark (such as the perineum), a special-purpose wristband can substitute for a marked site. In practice,

this means that all patients (except as in paragraph 3 of this attachment) must have either their operative site marked or be wearing a special-purpose wristband, and that if a wristband is used that the wristband must be checked in the subsequent steps rather than the marked site. When a special-purpose wristband is substituted for a marked site, the anatomical site of the procedure and the name of the procedure must be written on the wristband. A special-purpose wristband with the name of the procedure and the site (without indicating the side) can also be substituted for a mark for cases when the side may be selected based on a real-time clinical decision, such as the insertion of a central vascular access device, e.g., a percutaneous intravascular catheter (PIC) line, in the left or right arm. If a wristband is used instead of marking a site, it must be affixed by the practitioner who will perform the procedure, or be initialed by the practitioner after being affixed by another member of the team.

5. In non-OR settings, the requirements as to the specific individuals (surgeon, circulating nurse, and anesthesia provider) that need to be involved in the "time out" are waived. Individuals participating in performing the procedure should participate in the timeout. The reality that in non-OR settings a procedure will sometimes be performed by one practitioner working alone is understood and there is no requirement to find a second person just to do a timeout. For dental extractions, the radiograph or a diagram of the mouth showing the tooth (teeth) planned for extraction should be reviewed with the dental assistant.

6. In non-OR settings, the requirement for two members of the team to perform the "Review Imaging Data" check is waived in cases when one practitioner will perform the procedure.

7. In non-OR settings, the procedures performed to ensure correct invasive procedures must be documented consistent with VHA-wide and local requirements. Documenting and retaining the signature consent is a VHA-wide requirement. The other steps need to be documented based on local methods, for example a facility or Veterans Integrated Service Network (VISN)- developed checklist may be used, or the fact that the site was marked and the other steps performed may be recorded in the progress notes according to standard processes at the facility.

ATTACHMENT E

DEFINITION OF SURGICAL OR OTHER INVASIVE PROCEDURES

1. Surgical or other invasive procedures are those involving a skin incision or puncture including, but not limited to: open surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, endoscopies, and excluding venipuncture or intravenous therapy.

2. To provide clarity as to the types of procedures that are subject to this Directive, in addition to open surgery and other unambiguously surgical procedures, specific examples of other invasive procedures that require the use the standard or a condensed version of the five steps for ensuring correct surgery are provided as follows:

a. Injections of any substance into a joint space or body cavity;

b. Percutaneous aspiration of body fluids through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization);

c. Biopsy (e.g., breast, liver, muscle, kidney, genitourinary, prostate, bladder, skin);

d. Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent implantation, intra-aortic balloon catheter insertion);

e. Central vascular access device insertion (e.g., Swan-Ganz catheter, percutaneous intravascular catheter (PIC) line, Hickman catheter);

f. Electrocautery of skin lesion;

g. Endoscopy (e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, Percutaneous Endoscopic Gastrostomy (PEG), and J-tube placements, nephrostomy tube placements);

h. Laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy, laparoscopic nephrectomy);

i. Invasive radiology procedures (e.g., angiography, angioplasty, percutaneous biopsy);

j. Laser therapy (e.g., eye, Ear, nose, and throat (ENT));

k. Dermatology Procedures (biopsy, excision and deep cryotherapy for malignant lesions - excluding cryotherapy for benign lesions);

l. Invasive ophthalmic procedures, including miscellaneous procedures involving implants;

m. Oral surgical procedures including tooth extraction and gingival biopsy, except as noted in Attachments A and D;

n. Podiatric invasive procedures (removal of ingrown toenail, etc.); and

o. Skin or wound debridement performed in an operating room.

NOTE: *Procedures similar in scope to those listed in the preceding need to be considered invasive procedures and subject to the requirements of this Directive.*

ATTACHMENT F

SAMPLE FACILITY POLICY DIRECTIVE

CORRECT-SITE SURGERY PROCEDURES

1. PURPOSE: This (Name) Department of Veterans Affairs (VA) Medical Center Policy Directive establishes effective identification of the correct site, patient, and implant for a surgical or invasive procedure.

2. POLICY: This VA Medical Center policy establishes a procedure to significantly reduce the possibility of wrong-site, wrong-patient, or wrong implant surgical or invasive procedures.

3. ACTION

a. The physician or other privileged provider must:

(1) advise the patient or surrogate decision maker of the required procedure and identify the body part directly involved. This information must be recorded in the patient's medical record.

(2) review the following data after scheduling the patient for surgery and prior to the surgery or invasive procedure:

(a) x-rays (and other imaging reports).

(b) pre-procedure history and physical (H&P), and other clinically relevant material (i.e., consults, progress notes, laboratory values, etc.) in the patient's medical record.

b. Ensure that a VA authorized consent form is signed by the patient (or the individual authorized by VA policy to consent on behalf of the patient), and states the procedure site (location), including laterality (side), if applicable; the name and a brief description of the procedure; and the reason (condition or diagnosis) for which the procedure is being performed. The explanation of the procedure should be in terms that the patient understands. ***NOTE:*** *Abbreviations are not to be used; "right," "left," "both," etc., need to be written out using terminology intended to be understood by the patient.*

c. Ensure that prior to the patient entering the Operating Room (OR), a physician member of the patient's operating team (attending surgeon, resident, or fellow) marks the correct site, side, and location of the procedure with an appropriate marker. This must be done after asking a competent patient to state their full name, full social security number, and the location on the body where the patient understands the procedure will take place.

(1) For invasive procedures performed outside the operating room, the site must be marked prior to the procedure consistent with the requirements of VHA national policy. This policy requires that most sites of invasive procedures be marked, with the following exceptions:

(a) Endoscopic and other procedures performed through the mouth or anus performed in a non-OR setting;

(b) Oral surgery, tooth extractions, and other procedures where marking the site would require marking a mucous membrane rather than skin; and

(c) Procedures performed in non-OR settings where the practitioner is in the physical presence of the patient from the time of signature consent through to the time when the procedures is performed.

(2) A special-purpose wristband can be substituted for a mark when the side is uncertain at the time when the site would be marked. Examples include cardiac catheters that may be placed in the left or right groin or PIC lines that may be inserted in the left or right arm.

d. Ensure that the site must be marked with the physician's initials, except in special cases where a smaller mark is desired (for example, near the eye).

e. Ensure that the mark is placed on the patient's body in consultation with the patient and after confirming the identity of the patient with the patient. In a patient that lacks decision-making capacity, when possible, the surgeon needs to ask the authorized surrogate to state the name of the patient and confirm the operative site and side. The surgeon then marks the correct site according to facility policy. For sites that are awkward or potentially embarrassing to mark, such as the perineum, a special purpose wristband can be substituted for a marked site to indicate the site. In these cases the site and the procedure must be written on the wristband.

f. Ensure that whenever possible, the mark is placed so that it is visible in the operative field after the site is prepped and draped. In the case of multiple level surgeries, for example spine surgery, the levels that are to be operated on need to be written next to the mark.

g. Ensure that for spinal surgery, when marking a site with a pen is frequently inadequate to indicate the vertebral body or intervetebral space that will be operated on, procedures identified by the American Academy of Orthopedic Surgeons (AAOS) are followed: "In spine surgery or when the bone or level is not identifiable visually, surgeon takes an intraoperative X-ray using markers that do not move to confirm the site." (see AAOS Advisory Statement 1015, October 2003).

h. Ensure that, to avoid confusion, non-operative sites or sides <u>are not to be marked</u>, unless required for another aspect of care. Mucous membranes are not to be marked. Patients scheduled for Gastrointestinal (GI) endoscopy do not have their site marked, but all other steps described in this Directive apply.

(1) Outpatients and Same-day Admittance patients are to have the site marked in the pre-care area prior to the procedure.

(2) Inpatients may have their site marked in their rooms. Alternatively, after transportation by the OR team they may have the site marked prior to the procedure in the pre-care area.

(3) Intensive Care Unit patients, including Emergency Care Service patients, are to have the site marked in their respective units prior to patient transport to the OR for the procedure.

(4) In the event of a life-threatening emergency, the site need not be marked prior to transporting the patient to the OR; however, the surgical team must concur about the correct operative site in the OR prior to the initiation of surgery.

i. Ensure that immediately before the patient enters the OR, a physician, nurse, physician assistant or medical technician associated with the care of the patient asks the patient to state the patient's full name, full social security number or birth date, and to identify the operative site. The responses must be checked against the VA authorized consent form, the identification bands, and other documents. This validation must be documented on the Pre-operative Checklist prior to the patient's transfer to the OR; the staff member who performs this check must stay with the patient until the patient is brought into the OR. ***NOTE:*** *For procedures done outside an OR this step should be performed shortly before the procedure at a time appropriately integrated into the other preparatory steps.*

j. Ensure that, prior to the start of the procedure, two members of the OR team verify and document any imaging data that is used to confirm that the site is correct, is properly labeled with the patient's name and the correct side of the anatomy, and properly presented or oriented (left or right and up and down). When a procedure is done outside an OR by a single provider there is no requirement to seek out a second provider to perform this confirmation – the sole provider may verify the imaging data alone.

k. Ensure that, as a final check ("time out") prior to the start of the procedure, at a time when the patient and the operating team are present in the OR, the presence of the correct patient, the correctly marked site, intended procedure, the required position of the patient (e.g., supine), and the correct implant (where applicable) must be verbally confirmed by the members of the operating room team (at a minimum, the surgeon, circulating nurse, and anesthesia provider). In cases involving special equipment or technology, the surgical technician should also be included in the time-out. The circulating nurse must document the completion of the time out. When a procedure is done outside an OR by a single provider, there is no requirement to seek out a second provider to perform this the timeout; the sole provider must check and verify the preceding patient data and identity alone. If a wristband is used instead of marking the site, the wristband must be accessible to be checked when the time out step occurs; this may preclude final site preparation before the timeout in some cases.

l. Ensure that except in cases of surgical or medical emergencies, or those rare situations where certain steps are impossible to complete, if any required action is found not to have been accomplished, the procedure must be delayed until the discrepancy is corrected. ***NOTE:*** *In the emergency or rare cases where the steps are not all followed, and the decision is made to allow the procedure to proceed, the justification for the deviation(s) must be documented.*

4. REFERENCES

a. JCAHO Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. Available at:

http://www.jcaho.com/accredited+organizations/patient+safety/universal+protocol/wss_universal+protocol.htm .

b. VHA Handbook 1004.1. VHA Informed Consent for Clinical Treatments and Procedures. Available at: http://vaww.va.gov/publ/direc/health/handbook/1004-1hk .

c. VHA Directive 2004-028, Ensuring Corrective Surgery and Invasive Procedures. Available at: *www.va.gov/publ/direc/health/publications* .

5. RESPONSIBLE OFFICE: The Chief of Staff, or designee, is responsible for the contents of this memorandum. Questions may be addressed to (use telephone number).

6. RECISSIONS: The former facility directive (use number and date of rescinded policy) is rescinded. This (Name) VA Medical Center Directive expires June 30, 2009.

John A. Doe, Director
VA Medical Center

ATTACHMENT G

ADDITIONAL STRATEGIES, TECHNIQUES, AND TOOLS TO HELP ENSURE CORRECT SURGERIES
(MORE MAY BE ADDED IN CONCERT WITH PILOT TEST SITES)

NOTE: *Any special steps taken to ensure a correct surgery, such as the following suggestions, must be recorded in the patient's medical record.*

1. Possible Enhancements to Minimum Pre-Operative Procedures (days to about an hour before surgery)

a. Confirm the site (including laterality if applicable) and the procedure during the telephone call that is typically made to an outpatient 24 to 48 hours before the scheduled procedure.

b. Add to or create a guidebook for patients on what to expect related to their role in ensuring correct surgeries. Or consistently distribute the brochure developed by the VHA National Center for Patient Safety on this topic.

c. Standardize a check of the consent form against the Operating Room (OR) schedule 24 hours in advance.

d. Use no abbreviations or acronyms on the consent form or other crucial documents.

e. Do not accept illegible handwriting on the consent form or other crucial documents.

2. Possible Enhancements to Minimum Immediately Pre-Operative Procedures (usually an hour or less before surgery). When asking the patient to verbally state the site, ask the patient to indicate the site by touching it too (as appropriate). This may be especially helpful in cases where disease exists on both sides (e.g., two arthritic knees or two eyes with cataracts), but only one side is scheduled for a procedure on that day.

3. Possible Enhancements to Minimum OR Procedures (minutes to seconds before surgery). Write the patient's name, the location of the site (including laterality), the name of the procedure, and the details of any implants that will be used (e.g., the diopter for an eye implant, the size of femoral head and acetabular component for a hip implant) on a white board or other easily visible place in the OR prior to the start of surgery. Refer to this text in the confirmation process before the start of surgery.

4. Possible Checklist for Documenting Steps in Non-OR Settings. A checklist may be developed.

ATTACHMENT H

FLOWCHART ON ENSURING CORRECT INVASIVE PROCEDURES IN ALL CLINICAL SETTINGS[1]